Remarks

Claims 1-42 are pending, with Claims 1-14 and 17-21 having been rejected and Claims 15, 16 and 22-42 having been withdrawn from consideration. Both a Request for Extension of Time and a Supplemental Information Disclosure Statement accompany this response.

Claims 1-42 have been rejected as being unpatentable on the ground of nonstatutory obviousness-type double patenting over U.S. Patent Nos. 6,582,724; 6,673,363; 6,835,392; and 6,586,000 in view of U.S. Patent No. 5,993,836; and provisionally rejected as being unpatentable over claims 51-52 of co-pending Application No. 10/863,432. Applicant requests that these rejections be held in abeyance until there is an indication of allowable subject matter, and then to be reconsidered under the impact of new rules regarding continuing and co-pending applications that might apply at the time.

The rejection of Claims 19-21 under Section 112, second paragraph, is respectfully traversed. The use of the terms "derivatives" and "irritation mitigating" are both well within the skill of those in the art, particularly when read in light of the specification. With regard to the former term, a cursory search of issued US patents shows over 26,000 that include the term "derivatives thereof" in their claims. With regard to the latter term, those skilled will most certainly be able to determine whether an additive has the ability to affect, and particularly reduce, irritation.

The rejections under Sections 102 and 103 based on Hustead et al. ('970) are respectfully traversed. The reference appears to be cited largely for teaching a pH of up to 8.0, in the course of providing local anesthetics. Though NaOH is mentioned in the reference, it is clearly used in a very different manner, and for very different purposes than is presently described and claimed.

In fact, the Na cation is described as one of many possible anions to be used as counter ions to preferred "painless electrolytes" such as chloride and acetate. OH, in turn, itself is merely part of the buffering system used to keep the composition at or near neutral pH (see, e.g., col. 3, lines 20-23). Clearly nothing in this reference teaches or suggests a composition having, *inter alia*, inorganic base, such as sodium hydroxide, in an amount sufficient to provide a pH of about 8.0-13.0 at the body surface during administration of the local anesthetic agent, and in turn, enhance the flux of the local anesthetic agent through the body surface without causing damage thereto.

Finally, the rejection under Section 103 based on Yamanaka et al. ('497) is respectfully traversed. Yamanaka et al. is cited for teaching a medicated plaster containing an active agent and a basic substance (e.g., sodium hydroxide or potassium hydroxide) to keep a pH of 7 or higher. Yamanaka et al. describe three different combinations, all of which contain either an acid or an acid group (col. 8, lines 51-57). The reference itself states that the acid services to prevent the decline of medicine over time. Given that Yamanaka et al. require the presence of an acid to maintain the system during storage, there is nothing in the reference that suggests including an enhancing and a neutralizing amount of a hydroxide-releasing agent.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Commissioner is hereby authorized to charge any additional fees required to Deposit Account No. 061910.

Respectfully submitted,

Dated: October 1, 2007

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